UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EUGENE SHAPIRO, Individually and on Behalf of All Others Similarly Situated, Plaintiff, -v- TG THERAPEUTICS, INC., MICHAEL S. WEISS, SEAN A. POWER, and ADAM WALDMAN, Defendants.	22-cv-6106 (JSR) OPINION AND ORDER

JED S. RAKOFF, U.S.D.J.:

This is a putative class action brought against TG Therapeutics, Inc. ("TG Therapeutics"), a biotechnology firm, and three of its officers, Michael Weiss, Sean Power, and Adam Waldman (collectively, the "Individual Defendants"). The First Amended Complaint ("FAC") alleges that the defendants made false and misleading statements relating to the development of two new drugs, Ublituximab and Umbralisib. Plaintiffs allege that defendants' misrepresentations violated (1) Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder; and (2) Section 20(a) of the Exchange Act.

On November 11, 2022, defendants moved to dismiss the First Amended Complaint for failure to state a claim. See ECF No. 52. After full briefing, the Court held oral argument on defendants'

motion on December 21, 2022. On January 13, 2023, the Court granted defendants' motion in a "bottom-line" order, promising that an opinion would follow explaining the reasons for that order. Here is that Opinion.

I. Plaintiff's Allegations

TG Therapeutics is a biopharmaceutical company. FAC, ¶ 2. It focuses on treatments for B-cell malignancies and autoimmune diseases such as cancer and multiple sclerosis. Id. Its common stock trades on the NASDAQ Stock Market. Id. at ¶ 55.

By February 2021, TG Therapeutics had developed two drug candidates, Umbralisib (known in the business as "UKONIQ") and Ublituximab. FAC, ¶¶ 2,4. On their own, UKONIQ and Ublituximab had shown promise as potential treatments for certain kinds of lymphoma and multiple sclerosis, respectively. FAC, ¶ 3. But TG Therapeutics had even greater ambitions for them. TG Therapeutics believed that when UKONIQ and Ublituximab were combined (in a package called "U2"), they could jointly treat certain kinds of leukemia and perhaps other B-cell disorders as well. FAC, ¶ 3. Investors believed that U2 had "blockbuster potential." FAC, ¶ 4.

But, the First Amended Complaint alleges, UKNONIQ (and, therefore, U2) also posed risks to patients' health. FAC, ¶ 6. UKONIQ treated patients by inhibiting the PI3K receptor. This pharmaceutical mechanism was known to pose risks of serious side-

effects. FAC, ¶ 6. In light of these and other risks, the Food and Drug Administration ("FDA") required TG Therapeutics to submit a New Drug Application ("NDA") or a Biologics License Application ("BLA") with respect to these treatments for FDA approval before the treatments could be brought to market. FAC, ¶¶ 6-8, 75.

To secure FDA approval, TG Therapeutics submitted UKONIQ and U2 to a series of clinical trials. FAC, ¶¶ 79-81. As alleged in the First Amended Complaint, these trials revealed that patients suffered many "adverse events" and "serious adverse events" -- such as hospitalization, life-threatening illnesses, and death -- when they took UKONIQ and U2. FAC, ¶ 13. TG Therapeutics tracked such adverse events and serious adverse events that arose and reported them to the FDA. FAC, ¶ 14. These (serious) adverse events were logged in the FDA Adverse Event Reporting System, which is publicly available. FAC, ¶ 95. While clinical trials were still ongoing, TG Therapeutics touted the fact that the FDA had put UKONIQ on an accelerated timeline for approval, and it repeatedly asserted that UKONIQ was safe. FAC, ¶¶ 17-26.

On November 30, 2021, TG Therapeutics disclosed that the FDA had concerns about the safety of U2. More specifically, TG Therapeutics disclosed that the FDA planned to host a meeting of the Oncologic Drugs Advisory Committee ("ODAC") in connection with its review of the U2 BLA and NDA for the treatment of chronic lymphoma leukemia. FAC, ¶ 32. On this news, the price of TG

Therapeutics' stock declined by $8.16 per share, or approximately 34.93%. FAC, ¶ 34.

More bad news followed. On April 15, 2022, TG Therapeutics announced that it had voluntarily withdrawn the biologics license application and the supplemental new drugs application for U2. FAC, ¶ 214. Just before market opening on April 18, 2022, TG Therapeutics also announced that it was shuttering its oncology division. Id. On this news, TG Therapeutics' stock price fell by $1.93 per share, or 21.81%, to close at $6.92 per share on April 18, 2022. Id. At ¶ 217. On May 31, 2022, TG Therapeutics disclosed that the FDA had pushed back a key milestone for approval of Ublituximab, after which the price of TG Therapeutics' stock fell by $0.75 per share, or 14.51%. Id. At ¶ 221. Finally, on June 1, 2022, the FDA revealed that it had removed its approval of UKONIQ due to concerns about UKONIQ's safety. Id. At ¶ 228. The price of TG Therapeutics' stock fell by a further $0.51 per share, or 11.54%. Id. At ¶ 230.

On July 18, 2022, Mr. Shapiro filed the Complaint, which was subsequently amended on October 28, 2022. The First Amended Complaint asserts two claims:

(1) That TG Therapeutics, as well as the Individual Defendants, made false or misleading statements of material fact, in violation of

Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder; and

(2) That the Individual Defendants violated Section 20(a) of the Exchange Act by controlling TG Therapeutics when it made false or misleading statements of material fact. Id. ¶¶ 265-76.

II. Discussion

Defendants move to dismiss all claims asserted in the First Amended Complaint. To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim that is plausible on its face.' " Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "In considering a motion to dismiss ... the court is to accept as true all facts alleged in the complaint" and must "draw all reasonable inferences in favor of the plaintiff." Kassner v. 2nd Ave. Delicatessen Inc., 496 F.3d 229, 237 (2d Cir. 2007). However, mere conclusory statements and "formulaic recitation[s] of the elements of a cause of action" will not suffice. Twombly, 550 U.S. at 555.

Furthermore, Section 10(b) claims are subject to the heightened pleading standards of Rule 9(b) and the PSLRA. Accordingly, to state a claim for violation of Section 10(b), a plaintiff must "state with particularity the circumstances

constituting fraud or mistake." Fed. R. Civ. P. 9(b). The Second Circuit has interpreted Rule 9(b) to require that a complaint "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Rombach v. Chang, 355 F.3d 164, 170 (2d Cir. 2004) (citation and internal quotation marks omitted). In addition, under the PSLRA, the plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1).

There are six elements of a private claim brought under Section 10(b). A plaintiff must prove: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." Levitt v. J.P. Morgan Sec., Inc., 710 F.3d 454, 465 (2d Cir. 2013).

A. Omissions

The First Amended Complaint alleges that defendants made statements that were materially false and misleading because those statements did not disclose the serious adverse events that arose in clinical trials of UKONIQ. Id. ¶ 18.

Section 10(b) does not impose a per se duty to disclose information. Rather, "for an omission to be considered actionable under § 10(b), the defendant must be subject to an underlying duty to disclose." Levitt, 710 F.3d at 465. Such a duty may arise when "a corporate statement . . . would otherwise be inaccurate, incomplete, or misleading." Stratte-McClure v. Morgan Stanley, 776 F.3d 94, 101 (2d Cir. 2015). In other words, although "Rule 10b-5 imposes no duty to disclose all material, nonpublic information, once a party chooses to speak, it has a duty to be both accurate and complete." Plumbers' Union Loc. No. 12 Pension Fund v. Swiss Reinsurance Co., 753 F. Supp. 2d 166, 180 (S.D.N.Y. 2010). The standard of materiality is whether the omitted fact "would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988).

1. Analysis

Defendants argue their omission of adverse events in press releases was not material, because TG Therapeutics had already disclosed those adverse events to the FDA's Adverse Event Reporting System, which is publicly accessible. Thus, the occurrence of the serious adverse events was already in the public domain. Further disclosure in the form of press releases would not have

"significantly altered the total mix of information" available to a reasonable investor.[1]

Mr. Shapiro responds that disclosure to the FDA's Adverse Event Reporting System was insufficient. Material facts must be conveyed to the public "with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information created by alleged misstatements." In re MBIA, Inc., Sec. Litig., 700 F. Supp. 2d 566, 581-84 (S.D.N.Y. 2010). Moreover, according to Mr. Shapiro, there is some evidence that the significant adverse events were not disclosed with the requisite intensity: Because the price of TG Therapeutics' stock declined precipitously when TG Therapeutics announced that the FDA planned to host an ODAC meeting in connection with its review of the U2 BLA and NDA, on November 30, 2021, it can be inferred that investors were surprised to learn that UKONIQ was as unsafe as the serious adverse events indicated.

But this is a weak argument. There is another explanation of why TG Therapeutics stock price declined so much on November 30, 2021. The market had already priced in the raw frequency of the adverse events, which had been logged in the FDA Adverse Event Reporting System. The mere fact that those events occurred,

[1] Defendants also argue that the significant adverse events were not material because, for various reasons, they would not have significantly altered the total mix of information even if they were not publicly availability. Because the Court finds that the public availability of the significant adverse events is dispositive, it need not address these arguments.

however, did not foreclose the possibility of FDA approval. Investors still expected a substantial likelihood that the FDA would analyze the adverse events, deem UKONIQ to be tolerably safe, and allow U2 to continue on the path towards regulatory approval. TG Therapeutics' disclosure of the ODAC meeting dashed those hopes.

Securities law presumes that the "market price of shares . . . reflects all publicly available information." Basic, 485 U.S. at 246. Against this presumption, Mr. Shapiro's argument makes little sense. If the adverse events that arose during the clinical trials of UKONIQ really were as threatening as Mr. Shapiro claims they were, but were stashed away in an inscrutable yet still accessible database, someone could have made a lot of money by reading the tea leaves. Because the market for shares traded on NASDAQ is, in general, efficient, and because drug candidates regularly go through the winnowing of the FDA regulatory process, it is very unlikely that this opportunity for arbitrage existed. Instead, the unavoidable inference is that the adverse events were already priced into TG Therapeutics' shares and that further disclosure of them would not have significantly altered a reasonable investor's total mix of information. For that reason, the First Amended Complaint fails to state a claim for wrongful omission under Section 10(b).

B. Misstatements

The First Amended Complaint also asserts the defendants made several statements that were materially false. These allegedly wrongful misstatements concerned both the safety of UKNONIQ and U2 and the prospects of FDA approval for U2.

Rule 10b-5 makes it unlawful to "make any untrue statement of a material fact." 17 C.F.R. § 240.10b-5. A fact is material if there is a "substantial likelihood that the disclosure of . . . omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988). "At the pleading stage, a plaintiff satisfies the material requirement of Rule 10b-5 by alleging a statement or omission that a reasonable investor would have considered significant in making investment decisions." Ganino v. Citizens Utils. Co., 228 F.3d 154, 161 (2d Cir. 2000).

In addition to this general rule, certain categories of statements are per se unactionable. As relevant here, "forward-looking statements" -- statements about what might or will happen in the future -- are not actionable if they are: (1) "identified and accompanied by meaningful cautionary language," (2) "immaterial," or (3) where plaintiffs fail to prove the statement was "made with actual knowledge that it was false or misleading." Slayton v. Am. Exp. Co., 604 F.3d 758, 766 (2d Cir. 2010).

Additionally, opinions are not actionable unless either (i) the speaker did not subjectively believe the opinion; (ii) the opinion contained one or more embedded factual statements that was false; or (iii) the statement failed to provide "critical context," meaning that the speaker implied he or she had a reasonable basis for the opinion but in fact did not. Abramson v. Newlink Genetics Corp., 965 F.3d 165, 175 (2d Cir. 2020).

Some of the defendants' allegedly wrongful misstatements are not actionable because they are covered by the PSLRA safe harbor for forward-looking statements. These statements include:

> **March 2, 2021 Press Release:** 2020 was a year of data and regulatory execution for us as we delivered results from our UNITY-NHL study that led to the approval of UKONIQ in relapsed/refractory MZL and FL and from UNITY-CLL that will be used to support the current rolling BLA submission for ublituximab in combination with umbralisib for patients with CLL . . . These successful outcomes were made possible by the hard work of everyone at TG over many years and has positioned us for an exciting 2021 . . . With the UKONIQ launch underway, we are excited to keep the momentum going and expect this year to complete our BLA submission for U2 in CLL . . . FAC, ¶ 163.

> **August 2, 2021 Press Release:** We are pleased with the progress made throughout the second quarter, including our ongoing launch of UKONIQ in relapsed or refractory MZL and FL, FDA's acceptance of our BLA/sNDA for the combination of ublituximab and UKONIQ (U2) to treat CLL and SLL, and the continued advancement of our clinical programs. We have built a strong commercialization infrastructure to launch UKONIQ and have received positive feedback from healthcare providers on their experiences with the product and with the TG team. We believe this solid commercialization foundation will support, if approved, the launch of U2 in CLL. FAC, ¶ 169.

> **September 23, 2021 Press Release:** We are pleased that the integrated safety analysis of 371 patients treated with UKONIQ has been published in Blood Advances. We believe these data further support the differentiated safety profile of UKONIQ, the first and only PI3k-delta and CK1-epsilon inhibitor, which is now commercially available to patients with relapsed or refractory marginal zone lymphoma and follicular lymphoma. As we strive toward obtaining FDA approval of the investigational combination of UKONIQ and ublituximab, U2, in CLL by the PDUFA goal date of March 25, 2022, furthering our understanding of the safety and tolerability profile of UKONIQ remains paramount to us. FAC, ¶ 171.

Each of these statements concerns prospective FDA approval of U2, and "[p]rojections about the likelihood of FDA approval are forward-looking statements." Kovtun v. VIVUS, Inc., No. C 10-4957 PJH, 2012 WL 4477647, at *12 (N.D. Cal. Sept. 27, 2012), aff'd sub nom. Ingram v. VIVUS, Inc., 591 F. App'x 592 (9th Cir. 2015). TG Therapeutics identified these statements as forward-looking and repeatedly insisted both that FDA approval was not assured and that FDA approval could be jeopardized by further results from clinical trials. These statements are, therefore, protected by the PSLRA's safe harbor for forward-looking statements.[2]

These statements, however, are not the only ones alleged to be materially false. Mr. Shapiro also argues that defendants made statements that were materially false insofar as they claimed that UKONIQ was safe (or, perhaps safer than other PI3k inhibitors).

[2] Mr. Shapiro argues that the safe harbor for forward-looking statements does not apply to these statements, because the declarants knew that the statements were false. However, for reasons discussed more fully below, the allegations in the First Amended Complaint do not support a finding that the declarants knew that UKONIQ was unsafe.

More specifically, Mr. Shapiro argues that the following statements are actionable:

> **Q1 2021 Earnings Call:** Through market research, advisory boards, and our field team engagements, we have confirmed that UKONIQ is a different - is seen as a differentiated product. We've consistently heard that the proven efficacy across marginal zone and follicular, its unique MOA, tolerable safety profile, low rates of discontinuation, and a lack of a black-box warning are important differentiators with health care providers and payers. We believe that these factors help establish UKONIQ in a class of its own. See FAC, ¶ 111.
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> **September 23, 2021 Press Release:** We are pleased that the integrated safety analysis of 371 patients treated with UKONIQ has been published in Blood Advances. We believe these data further support the differentiated safety profile of UKONIQ, the first and only PI3k-delta and CK1-epsilon inhibitor, which is now commercially available to patients with relapsed or refractory marginal zone lymphoma and follicular lymphoma. As we strive toward obtaining FDA approval of the investigational combination of UKONIQ and ublituximab, U2, in CLL by the PDUFA goal date of March 25, 2022, furthering our understanding of the safety and tolerability profile of UKONIQ remains paramount to us. See FAC, at ¶ 120.

As a threshold matter, defendants argue that these statements are not actionable because they are statements of opinion. As defendants point out, certain of the assertions in these statements are prefaced by "we believe," which is a tell-tale sign of an opinion. See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 183-84 (2015).

Mr. Shapiro responds that both of these statements contain many assertions that are not prefaced by phrases like "we believe."

Additionally, he argues that even those assertions that are opinions qualify for one of the Abramson exceptions. According to Mr. Shapiro, the opinion that "UKONIQ [was] in a class of its own" contains false embedded facts, since it implies that UKONIQ was safe. So too for the statement that UKONIQ has a "differentiated safety profile."

Even if Mr. Shapiro is right on these points, however, his claims for fraudulent misstatement cannot go forward unless the First Amended Complaint "state[s] with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The required state of mind is "scienter" -- that is, an intent "to deceive, manipulate, or defraud." Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 313 (2007). For the inference of scienter to be "strong," the inference must be such that "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id. at 314. The First Amended Complaint may satisfy this burden by alleging facts "(1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007). The First Amended Complaint does not plead sufficient facts to support a strong inference of scienter.

In order to allege motive, a plaintiff must allege a "concrete and personal benefit" from the misrepresentations or omissions. Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001). While this element is not satisfied merely by an allegation of a "motive possessed by virtually all corporate insiders," it is satisfied by an allegation that the defendants "benefited in some concrete and personal way from the purported fraud." Novak v. Kasaks, 216 F.3d 300, 307 (2d Cir. 2000). Thus, for example, the mere desire "to maintain a high stock price in order to increase executive compensation" is not a sufficient motive, but the allegation that corporate insiders misled the public "in order to keep the stock price artificially high while they sold their own shares at a profit" is. Id. at 308.

The facts alleged in the First Amended Complaint concerning the Individual Defendants' compensation do support a strong inference of scienter. The First Amended Complaint alleges that defendants Weiss and Power would have received cash bonuses for meeting certain milestones regarding FDA approval of U2 and UKONIQ. FAC, ¶ 237. These bonuses certainly would have provided those defendants with a strong incentive to conceal adverse events from the FDA. But Mr. Shapiro does not claim that the defendants defrauded the FDA; he claims that they defrauded the public. And cash bonuses triggered by regulatory milestones did not provide defendants Weiss and Power with much of an incentive to conceal

adverse events from the public. The First Amended Complaint does not allege that TG Therapeutics was anything less than fully forthcoming in its reporting of adverse events to the FDA's Adverse Event Reporting System. That being so, keeping adverse events from the public would not have assisted much with securing FDA approval. The FDA would have known anyway.

The facts alleged in the First Amended Complaint also do not provide "strong circumstantial evidence of conscious behavior or recklessness." ATSI, 493 F.3d at 99. The First Amended Complaint does plead facts that indicate that the defendants knew about many of the adverse events that arose during clinical trials of UKONIQ. FAC, ¶¶ 28, 118. But the defendants concede that they knew about those adverse events. Conference of Dec. 21, 2023, Tr. 4:8-11. Even if they had such knowledge, it does not follow that they knew that UKONIQ was unsafe (or were reckless with respect to its safety). Adverse events during clinical trials are raw data. A certain number of such events are to be expected, especially during a clinical trial of a drug candidate, such as UKONIQ, that is intended to be used by gravely ill patients. See Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 43 (2011) ("Adverse event reports are daily events in the pharmaceutical industry. . . . The fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event."). Thus, the mere occurrence of adverse events did not give the

defendants knowledge that UKNOIQ was unsafe, and the defendants were not reckless in touting UKONIQ's safety simply because those adverse events occurred.[3]

Put together, the facts alleged in the First Amended Complaint do not support a strong inference of scienter. Thus, the First Amended Complaint fails to state a claim for fraudulent misstatement.

C. Control Person Violations

Mr. Shapiro also claims that the Individual Defendants violated Section 20(a) of the Exchange Act because they had control over TG Therapeutics when it allegedly violated Section 10(b) by making materially false omissions and misstatements. Since this allegation presupposes that TG Therapeutics violated Section 10(b) of the Exchange Act, and since the First Amended Complaint fails to state a claim for such a violation, Mr. Shapiro's Section 20(a) claim must also be dismissed.

III. Conclusion

For the foregoing reasons, the First Amended Complaint fails to state a claim on which relief can be granted. Thus, the Court

[3] The First Amended Complaint does allege that the defendants did eventually know that the "hazard ratio" exhibited in clinical trials of UKONIQ exceeded 1.00, meaning that patients who received UKNONIQ were more likely to die than patients who were in the control arm of the clinical trials. FAC, ¶ 124. However, the First Amended Complaint does not allege that the defendants knew of this hazard ratio at the time that they were making their allegedly wrongful statements concerning the safety of UKONIQ.

reaffirms its Order of January 13, 2023 and hereby dismisses the First Amended Complaint, without leave to amend.

The Clerk is respectfully directed to enter judgment and close the case.

SO ORDERED.

Dated: New York, NY

January 25, 2023

JED S. RAKOFF, U.S.D.J.